Remarks/Arguments

Claims 12, 13 and 15 to 26 are pending. New Claims 20 to 26 have been added. Claim 18 has been amended.

The Office Action stated that the following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 to 19 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants traverse, in part, this rejection.

The Office Action stated that Claims 15 to 19 are indefinite since these claims cover compositions, by virtue of the fact that these claims either require a solid (e.g., Claim 15) or a pasty (e.g., Claim 17), while Claim 12, from which the rejected claims depend, covers a compound, and thus, those of ordinary skill would not know if the rejected claims cover compounds or compositions. Applicants traverse this statement as being incorrect in several important aspects.

A compound has several physical states, for example, solid, liquid, etc. Claim 12 covers a compound so Claim 12 covers such compound in all of its physical states. Claim 15 claims such compound in its solid state, so Claim 15 is not drawn to a composition (as opposed to a compound). Note however that Claim 12 covers such compound even when water, other compounds, elements,

etc., are present with such compound, in whatever physical stage it might be in. The scope of Claim 15 is the same except that at least part of such compound has to be in the solid state.

The Office Action stated: that Claim 17, for example requires that the carnitine-magnesium hyroxycitrate is pasty; and that the term pasty is indefinite since those of ordinary skill would not be appraised of the term pasty, i.e., the exact water content of the claimed composition is not known. Applicants traverse this statement.

The term pasty is not indefinite and it is defined in detail by applicants. Applicants' specification states:

> "For the purposes of the present invention, pasty is thus regarded as a composition which is flowable only under elevated pressure (> 1 bar) and at a minimum of 85 °C, in the sense of flow characteristics referred to as extrusion viscosity. The pasty composition is movable in the hot state by suitable apparatuses with an adequate torque. Definitive solidification takes place only through cooling." [Emphasis Supplied] [Page 8, lines 4 to 11]

As used in applicants' specification and claims, the term pasty is definite and refers to flowability and extrusion viscosity (and does not refer to some exact water content). In the sense of this definition of the term pasty, applicants' compound or composition can be pasty because such compound could have the required flowability at elevated pressure and at a temperature of 85 °C.

Accordingly, Claims 15 and 17 (plus Claims 16 and 18) are not indefinite because of the use of the terms solid and pasty.

New Claims 20 to 25 have been added as being composition claims corresponding to Claims 12, 13 and 15 to 20.

The Office Action stated that Claim 18 depends on itself. This matter has been corrected.

This rejection should be withdrawn.

The Office Action stated that the claims cover, inter alia, carnitine-magnesium hydroxycitrate, wherein the magnesium, carnitine and the hydroxycitrate are present in a molar ratio 1:1:1.

The Office Action stated that the claims also cover those embodiments wherein the carnitine is L-carnitine.

The Office Action stated that the claims also cover those embodiments wherein the carnitine-magnesium hydroxycitrate is a solid.

The Office Action stated that the claims also cover those embodiments wherein the carnitine-magnesium hydroxycitrate is pasty.

The Office Action stated that the claims also cover a product by process for preparing the claimed carnitine-magnesium hydroxycitrate.

The Office Action stated that the following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

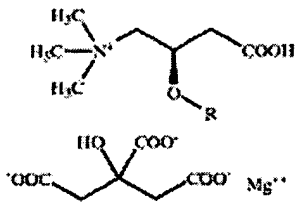
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the difference between the subject matter sought to be patented and the prior art are such that the subjection matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12, 13, and 15 to 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/44918, as evidenced by U.S. Patent No. 6,337,349 (Scafetta et al.). Applicants traverse this rejection.

The Office Action stated that Scafetta et al. teaches the following compounds at column 2:

(I)



wherein R is straight or branched lower alkanoyl having 2 to 5 carbon atoms. The compounds of Scafetta et al. do not teach or suggest any of applicants' claimed compounds or compositions. Scafetta et al. discloses citrate (one-OH), but not hydroxycitrate (two-OH).

Scafetta et al. states:

> "U.S. Pat. No. 5,071,874 discloses L-carnitine magnesium citrate but does not teach anything as regards the possibility of preparing magnesium citrates of alkanoyl-L-carnitines, nor does it suggest that these salts, if any, would be non-hygroscopic and stable to prolonged storages. It should, furthermore, be noticed that when a non-hygroscopic salt of L-carnitine is known, no conclusion can be drawn about the possibility of

obtaining similar salts of alkanoyl-L-carnitines from the same salifying acid. Indeed, e.g. L-(+)-tartaric acid which gives with L-carnitine a non-hygroscopic salt, is unable to give non-hygroscopic salts with the alkanoyl-L-carnitines, such as e.g. acetyl-L-carnitine." [Emphasis Supplied] [Col. 2, lines 26 to 38]

Scafetta et al. shows the unobviousness of applicants' claimed invention. See also column 2, lines 60 to 62, of Scafetta et al.

The Office Action stated that the example discloses that preparation of a solid which was concentrated by a vacuum. Applicants traverse this statement as being factually incorrect. In the example of Scafetta et al., the reaction solution was concentrated under vacuum—the physical state of the result of the concentrate was not given. The residue was taken up by acetone. The physical state of the residue was not given—it could have been a concentrated solution or suspension. The acetone mixture was "kept under stirring and then filtered"—there is no proof that such acetone mixture (liquid form??) would be in a pasty form (as defined by applicants' specification) since the acetone (boiling point: 56.5 °C) would likely be driven off at the definition measurement temperature of at least 85 °C. The example then recites that a solid was obtained.

The Office Action stated that, therefore, both solids and pasty preparations are disclosed. Applicants traverse this statement for the above reasons.

The Office Action stated that the difference between the compounds and compositions disclosed by Scafetta et al. and those covered by the instant claims, is that, while Scafetta et al. teaches alkanoyl carnitine-magnesium hydroxycitrates, the claims cover the non-acylated carnitines. Applicants

traverse this statement. Scafetta et al. does not disclose the use of hydroxycitrate and only discloses the use of citrate. Scafetta et al. directs one ordinarily skilled in the art away from applicants' claimed invention.

The Office Action stated that, however, Scafetta et al. teaches L-carnitines and its alkanoyl derivatives present the same therapeutic and nutritional activities (column 1, lines 18 to 23), and, therefore, those of ordinary skill would be motivated to modify the disclosed alkanoyl derivatives and substitute with L-carnitine. Applicants traverse this statement. The Examiner has not factually determined the level of ordinary skill in the art, so the Examiner knows nothing about one ordinarily skilled in the art or what would motivate such a person in the search for applicants' claimed invention.

Following the dictates of the Graham decision is mandatory of the Examiner. M.P.E.P. 2141, (rev. 2, May 2004), states:

> "Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103. As quoted above, the four factual inquiries enunciated therein as a background for determining obviousness are as follows:
>
> (A) Determining the scope and contents of the prior art;
>
> (B) Ascertaining the differences between the prior art and the claims in issue;
>
> (C) Resolving the level of ordinary skill in the pertinent art; and
>
> (D) Evaluating evidence of secondary considerations." [Emphasis Supplied]

M.P.E.P. 2141.03, (Rev. 2, May 2004), states:

"ASCERTAINING LEVEL OF ORDINARY SKILL IS NECESSARY TO MAINTAIN OBJECTIVITY"

"'The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry,' *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 USPQ2d 1043, 1057 (Fed. Cir. 1991). The examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984)." [Emphasis Supplied]

"M.P.E.P. 2144.08.II, (Rev. 2, May 2004), states:

"A proper obviousness analysis involves a three-step process. First, Office personnel should establish a *prima facie* case of unpatentability considering the factors set out by the Supreme Court in *Graham v. John Deere*. See, e.g., *In re Bell*. 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (The PTO bears the burden of establishing a case of *prima facie* obviousness.'); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966), requires that to make out a case of obviousness, one must:

(A) determine the scope and contents of the prior art;

(B) ascertain the differences between the prior art and the claims in issue;

(C) determine the level of skill in the pertinent art; and

(D) evaluate any evidence of secondary considerations. If a *prima facie* case is established, the burden shifts to applicant to come forward with rebuttal evidence or argument to overcome the *prima facie* case." [Emphasis Supplied]

The Office Action stated that, accordingly, Scafetta et al. teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success). Applicants traverse this statement. This Section 103(a) rejection is fatally defective. It materially misdescribed the disclosure of Scafetta et al. There has been no factual determination, as required by the Graham decision and Office policy, in the record of the level of ordinary skill in the art. Without this required factual determination, this obviousness rejection fails on its face. Accordingly, there is no prima facie showing of obviousness in the record.

The Office Action stated that Claim 12 is a product by process claim.

The Office Action stated that, in this connection, Scafetta et al. substantially teaches the claimed carnitine-magnesium hydroxycitrate, and, specifically, the record is silent with regard to any differences between the claimed compounds and compositions, and those suggested by Scafetta et al. This statement is clearly erroneous. Scafetta et al. does not disclose,

substantially or otherwise, hydroxycitrate so the Examiner's position is defective on its face.

Scafetta et al. does not teach or suggest the hydroxycitrate, substantially or otherwise. Section 103(a) requires facts, not factually unsupported assertions or speculation. The burden of proof is on the Examiner and he has not carried his burden of proof.

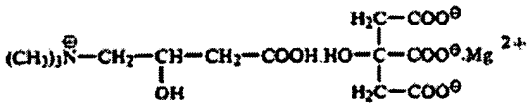
The Office Action stated see M.P.E.P. § ["'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thrope*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)... 'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974).'."]. Applicants traverse this statement. Since the Examiner has not made the necessary/required determination of the ordinary level of skill in the art, this Section 103(a) rejection is fatally defective. Hence, product-by-process Claim 12 has not been shown to be obvious.

This rejection should be withdrawn.

Claims 12, 13 and 15 to 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,071,874 (Scholl et al.) Applicants traverse this rejection.

Scholl et al. does not teach or suggest the inclusion of hydroxycitrate.

The Office Action stated that Scholl et al. teaches the following compounds of column 1:



Scholl et al. discloses citrate, not hydroxycitrate.

The Office Action states that the patent teaches that a solid is obtained by vacuum drying, thus disclosing pasty and solid compositions. This statement is not factually correct. The Examiner has not shown that Scholl et al. discloses any pasty composition within the meaning of such term as defined by applicants.

The Office Action stated see column 2, lines 30 to 44.

The Office Action stated that the difference between the compounds and compositions disclosed by Scholl et al. and those covered by the instant claims, is that while Scholl et al. teaches citrates, the claims cover hydroxycitrates. Applicants disagree. Scholl et al.'s citrate entity has one basic group and three acidic groups, whereas applicants' hydroxycitrate entity has two basic groups and three acidic groups. Column 2, lines 3 to 11, of U.S. Patent No. 4,602,039 teaches that a difference of such type often gives unexpected and surprising results regarding hygroscopicity/non-hygroscopicity in the field of carnitine

compounds/compositions. Applicants' claimed invention is unobvious over Scholl et al.

This and the other obviousness rejections are long on assertion and speculation, but lacking in the supporting facts required by Section 103(a).

The Office Action stated that, however, based on the disclosed citrates, the hydroxycitrate derivative is well within the motivation of those of ordinary skill. Applicants traverse this statement for several reasons. The assertion "well within the motivation of those of ordinary skill" has nothing to do with Section 103(a). Section 2143.01 of the M.P.E.P. states:

> "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." [Emphasis Supplied] [Page 2100-130]

The Examiner has not factually determined the level of ordinary skill in the art, so the Examiner cannot correctly any assertion concerning or involving one ordinarily skilled in the art. Nor has the Examiner factually shown in the record the so-called motivation of which the Examiner spoke. Section 2143.01 also states:

> **"FACT THAT THE CLAIMED INVENTION IS WITHIN THE CAPABILITIES OF ONE OF ORDINARY SKILL IN THE ART IS NOT SUFFICIENT BY ITSELF TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS"**

A statement that modifications of the prior art to meet the claimed invention would have been '"well within the ordinary skill of the art at the time the claimed invention was made"' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat.App. & Inter. 1993)." [Emphasis Supplied] [Page 2100-131]

"FACT THAT REFERENCES CAN BE COMBINED OR MODIFIED IS NOT SUFFICIENT TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS"

"The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)" [Page 2100-131]

The Office Action stated that, therefore, Scholl et al. teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggest all the claim limitations with a reasonable expectation of success). Applicants traverse this statement as being mere speculation. This rejection lacks a factual showing and analysis, for example, that Scholl et al. provides the so-called "reasonable expectation" of success. Furthermore, the Examiner has not factually determined in the record the level of ordinary skill in the art, hence there cannot be any showing of prima facie obviousness. This result showing the Examiner's

error is mandated by Office policy and the Graham decision. The Examiner still has not carried his burden of proof.

The Office Action stated that Claim 12 is a product by process claim.

The Office Action stated that, in this connection, Scholl et al. substantially teaches the claimed carnitine-magnesium hydroxycitrate, and, specifically, the record is silent with regard to any differences between the claimed compounds and compositions, and those suggested by Scholl et al. This statement is clearly erroneous. Scholl et al. does not disclose, substantial or otherwise, hydroxycitrate so the Examiner's position is defective on its face.

Scholl et al. does not teach or suggest the hydroxycitrate, substantially or otherwise. Section 103(a) requires facts, not factually unsupported assertions or speculation. The burden of proof is on the Examiner and he has not carried his burden of proof.

The Office Action stated see M.P.E.P. § ["'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) ... 'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974).'."]. Applicants traverse this

statement. Since the Examiner has not made the necessary/required determination of the ordinary level of skill in the art, this Section 103(a) rejection is fatally defective. Hence, product-by-process Claim 12 has not been shown to be obvious.

This rejection should be withdrawn.

Claims 12, 13 and 15 to 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the U.S. Patent Application Publication No. 2001/0011081 (Claudio). Applicants traverse this rejection.

Claudio does not teach or suggest the inclusion of hydroxycitrate.

The Office Action states that Claudio teaches the coordinated use of L-carnitine or an alkanoyl L-carnitine or the pharmacologically acceptable salts thereof with hydroxycitrate or pantothenic acid or derivatives thereof. Claudio does not teach or suggest that the L-carnitine (or salt thereof) and the hydroxycitrate (or derivative thereof) forms a salt/compound. The disclosure of Claudio directs towards them being separate entities ("a mixture of the aforesaid active ingredients", page 1, para. [0002], lines 10 and 11). Applicants claim a complex salt of three materials. Accordingly, Claudio directs one ordinarily skilled in the art away from applicants' claimed invention. This is so even when the hydroxycitrate is the calcium derivative thereof. This is so even when Claudio adds third compounds, that is, $FeSO_4$, $MnSO_4$, Zn acetate, $NazHPO_4$, molybdenum, potassium, chromium and selenium are added in Example 13, as separate entities.

The Office Action stated that "co-ordinated use" of the aforesaid compounds it is meant indifferently either the co-administration, i.e., the

substantially concomitant supplementation of L-carnitine or alkanoyl L-carnitine or a pharmacologically acceptable salt thereof and hydroxycitric or pantothenic acid or a derivative thereof, as active ingredients, or the administration of a combination preparation comprising a mixture of the aforesaid active ingredients, in addition to suitable excipients, if any. This statement shows that even the Examiner agrees that Claudio does not teach a salt of carnitine and hydroxycitrate. Claudio is relevant to the extent that it directs away from applicants' claimed invention.

The Office Action stated see paragraph 0002, first page. This supports applicants' position.

The Office Action stated that the difference between the compounds and compositions disclosed by Claudio and those covered by the instant claims, is that Claudio fails to explicitly teach magnesium salts. Applicants traverse this statement. Claudio does not even show a salt of carnitine and hydroxycitrate. Claudio does not teach or suggest a salt of such two compounds with any metal.

The Office Action stated that, however, Claudio does teach that any salt that does not give rise to undesirable side effects is suitable. Applicants traverse this statement as being an incorrect presentation of what Claudio discloses. Paragraph 0008 of Claudio only refers to acid addition salts of certain acids, none of which are disclosed to be hydrocitric acid [0009], with carnitine. The entire disclosure of Claudio is the carnitine entity and the hydroxycitrate entity are separate entities and are not combined together in salt form. Claudio directs against applicants' claimed invention.

The Office Action stated that, in this regard magnesium salts are known to be physiologically and pharmacologically acceptable, and thus, well within the motivation of those of ordinary skill. Applicants traverse this statement. The first part has no fact in the record to show such assertion re the claimed salts and compositions. The second part has been shown above to be meaningless under Section 103(a).

The Office Action stated that, therefore, Claudio teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success). Applicants traverse this statement as being mere speculation. This rejection lacks a factual showing and analysis, for example, that Scholl et al. provides the so-called reasonable expectation of success. Furthermore, the Examiner has not factually determined in the record the level of ordinary skill in the art, hence there cannot be any showing of prima facie obviousness. This result shows the Examiner's error is mandated by Office policy and the Graham decision. The Examiner still has not carried his burden of proof.

Claudio does not even disclose or suggest using a salt of carnitine and hydroxycitrate, Claudio's invention wants them as separate, unreacted entities. To assert otherwise is to destroy the very invention of Claudio.

The Office Action stated that Claim 12 is a product by process claim.

The Office Action stated that, in this connection, Claudio substantially teaches the claimed carnitine-magnesium hydroxycitrate, and specifically, the

record is silent with regard to any differences between the claimed compounds and compositions, and those suggested by Claudio. This statement is clearly erroneous. Claudio does not disclose, substantially or otherwise, hydroxycitrate so the Examiner's position is defective on its face.

Claudio does not teach or suggest the hydroxycitrate, substantially or otherwise. Section 103(a) requires facts, not factually unsupported assertions or speculation. The burden of proof is on the Examiner and he has not carried his burden of proof.

The Office Action stated see M.P.E.P. ["'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim in unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)... 'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324 (CCPA 1974).'."]. Applicants traverse this statement. Since the Examiner has not made the necessary/required determination of the ordinary level of skill in the art, this Section 103(a) rejection is fatally defective. Hence, product-by-process Claim 12 has not been shown to be obvious.

This rejection should be withdrawn.

Applicants' comparative data shows the error of the Section 103(a) rejections. The enclosed declaration of joint applicant Martin Fuhrmann sets out the comparative data/experiments in the application.

Reconsideration, reexamination and allowance of the claims are requested.

Respectfully submitted,

4/28/06
Date

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